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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------------|
| 10/761,387 | 01/22/2004 | Dennis M. Vigil | 12013/47103 | 2425 |
| 23838 | 7590 | 12/31/2007 | | |
| KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005 | | | EXAMINER BOUCHELLE, LAURA A | |
| | | | ART UNIT 3763 | PAPER NUMBER |
| | | | MAIL DATE 12/31/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/761,387 | VIGIL ET AL. | |
| | Examiner | Art Unit | |
| | Laura A. Bouchelle | 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7,9,10,12-14,17,19-23,26 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,9,10,12-14,17,19-23,26 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The appeal files 9/12/07 has been fully considered and is persuasive. Therefore, the finality of the previous action has been withdrawn. A new action on the merits follows.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 10, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil et al (US 5746716). Vigil discloses a method of releasing fluid medicament into a vessel wall comprising the steps of providing an expanding member 16 having a plurality of dispensers 20, advancing the expanding member through the vessel to the site, moving the expanding member from a first configuration to a second configuration, and releasing fluid medicament through the dispensers into the vessel wall (Col. 3, lines 50-65, Col. 5, lines 17-30).
3. Claims 1, 10, 20 differ from Vigil in calling for the dispensers to be provided in a single plane only. At the time the invention was made, it would have been an obvious matter of design choice to provide the dispensers in a single plane. Applicant has not disclosed that having the dispensers located in a single plane serves any advantage or particular purpose or solves a stated problem. Furthermore, one of ordinary skill would expect the device of Vigil and applicant's invention to perform equally well with dispensers located in a single or in multiple planes because both configurations treat a localized region of the vessel wall. Therefore, it would have been prima facie obvious to modify the device of Vigil to obtain the invention as specified in

claims 1, 10, 20 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

4. Claims 2, 3, 12, 13, 21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil in view of Rammler (WO 94/23787). Claims 2, 12, 21 differ from Vigil in calling for the fluid medicament to inhibit the proliferation of smooth tissue growth. Claims 3, 13, 22 differ in calling for the fluid medicament to include a radioactive isotope. Rammler teaches a balloon catheter for delivery of drugs to a site in a vessel comprising the step of delivering a cell proliferation inhibitor to prevent restenosis of the region (Page 6, line 35). Rammler also teaches that the balloon catheter may be used to deliver a radioactive isotope to provide for better definition of the vessel wall under fluoroscopy (Page 8, line 31). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Vigil to include the steps of delivering a cell proliferation inhibitor or a radioactive isotope as taught by Rammler to treat a vessel wall.

5. Claims 4, 14, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil in view of Goldberg et al (UUS 5480975). Claims 4, 14, 23 differ from Vigil in calling for the fluid medicament to stimulate production of collateral vessels. Goldberg teaches the use of a medicament that stimulates the production of collateral vessels to ameliorate hypoxic injury (Col. 2, lines 53-58). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Vigil to include the steps of delivering a medicament that stimulates the production of collateral vessels as taught by Goldberg to ameliorate hypoxic injury to tissues.

6. Claims 7, 17, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil in view of Casscells et al (WO 9211872). Claims 7, 17, 26 differ from Vigil in calling for the fluid medicament to comprise a binder. Casscells teaches the use of a binder that binds to the vessel wall so that drug agents can enter the target cells and destroy proliferating cells (see abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Vigil to include the steps of delivering a binder as taught by Casscells to allow drug agents to enter the target cells and destroy proliferating cells.

7. Claims 9, 19, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil in view of Nabel et al (US 5328470). Claims 9, 19, 28 differ from Vigil in calling for the medicament to comprise a gene for gene therapy. Nabel teaches the use of medicaments comprising a gene for gene therapy to a localized region of vessel injury (Col. 5, lines 60-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Vigil to include the step of providing a medicament having a gene for gene therapy as taught by Nabel to treat a localized region of vessel injury.

Response to Arguments

8. Applicant's arguments, see pre-brief request, filed 9/12/07, with respect to the rejection(s) of claim(s) 1, 10, 20 under March have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Vigil as above.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
Art Unit 3763



Tatyana Zalukaeva, Ph.D.
Primary Examiner
Art Unit ~~3763~~ 3761

